REMARKS

I. Status of the Application and Claims

Claims 1-20 and 24-35 are pending. As an initial matter, Applicants thank the Examiner for clarifying that claims 27-29 are considered to belong to Restriction Group II. The Examiner has made the Restriction Requirement final and states that "[c]laims 3, 4, 8, 10, 12-23 and 27-35 are being withdrawn from consideration." Office Action, page 2. Applicants note claims 21-23 were canceled in the Preliminary Amendment filed October 15, 2003. Claims 1, 2, 5-7, 9, 11 and 24-26 are under consideration.

II. Rejection Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 1, 2, 5-7, 9, 11 and 24-26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Office Action, page 2. According to the Office, "[i]t is not seen where the instant specification enables the ordinary artisan to choose which derivative of gemifloxacin to use in the instant claims." *Id.* The Office states that "the only enablement of 'a gemifloxacin compound' or its derivatives is from PCT/KR98/0051 published as WO 98/42705 or EP 688772." *Id.* at 3. The Office concludes, however, that the instant specification does not teach or enable the ordinary artisan to determine what is a gemifloxacin compound or its derivative because, according to the Office, the teachings of WO 98/42705 and EP 688772 "have not and cannot be incorporated into the specification." *Id.*

The Office confuses the nature of Applicants' invention. Applicants' invention relates to methods of using gemifloxacin and its derivatives. Applicants do not purport to have invented gemifloxacin or its derivatives. Rather, Applicants acknowledge in the "Background of the Invention" on pages 1-3 of the specification that gemifloxacin and its

derivatives were known. The specification and knowledge in the art, therefore, provide sufficient guidance with respect to gemifloxacin and its derivatives. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent *coupled with information known in the art* without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (emphasis added). The claims are limited to a new use of known compounds. In addition, the claims are not unreasonably broad in their scope, and the application disclosure provides all of the tools needed to practice the claimed methods. These factors weigh in favor of the presumptively enabling disclosure of the application. *See In re Wands*, 858 F.2d at 736-740; M.P.E.P. 2164.01(a). Because the Office has not provided any evidence or rationale to rebut this presumption, Applicants respectfully request the rejection be withdrawn.

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, 5-7, 9, 11 and 24-26 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as the invention. Office Action, page 4. The Office considers the terms "gemifloxacin" and "ciprofloxacin" to be Trademarks/common names for compounds, and suggests that the identity of the compounds known by these names may change over time. *Id.* The Office suggests Applicants amend the claims to define gemifloxacin and ciprofloxacin. *Id.* Applicants respectfully decline to amend the claims.

Neither gemifloxacin nor ciprofloxacin are trademarks. Ciprofloxacin is sold under the tradename CIPRO®, and gemifloxacin is sold under the tradename FACTIVE®. Gemifloxacin compounds are defined in the specification on page 4 at lines 30-32 as those compounds described in WO 98/42705 and EP 688772. Thus there is nothing indefinite about that term.

Ciprofloxacin is a well known in the art to be 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-quinoline-3-carboxylic acid. For example, U.S. Patent No. 4,957,922, issued over a decade ago, defines 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-quinoline-3-carboxylic acid as "ciprofloxacin" in column 1, at lines 10-13, then uses the term ciprofloxacin throughout the specification. The references already considered by the Examiner on Form PTO-1449 further establish that ciprofloxacin is an art-recognized and definite term. The Office has provided nothing but speculation that ciprofloxacin might someday possibly come to mean a different compound, based upon its erroneous belief that ciprofloxacin is a trademark, but this speculation does not establish that the term ciprofloxacin is indefinite.

The Office has failed to provide any evidence that the artisan would find either gemifloxacin or ciprofloxacin to be indefinite terms. Applicants therefore respectfully request the rejection be withdrawn.

IV. Rejection under 35 U.S.C. § 103

Claims 1, 2, 5-7, 9, 11 and 24-26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of U.S. Patent Nos. 5,633,262 and 5,776,944 (collectively "*Hong*"), U.S. Patent No. 6,262,071 ("*Crabb*"), Hohl and Kim.

Office Action, page 5. "*Hohl*" and "*Kim*" are said to be on the PTO-1449 provided by Applicants. *Id.* However, there are multiple references listed on Form PTO-1449 in which the first author is "Kim." Applicants request clarification as to which "Kim" reference the Office relies upon.

Contrary to the position of the Office in the rejection of the claims under 35 U.S.C. § 112, the Office now acknowledges gemifloxacin is a well-known antibacterial agent. Office Action, page 5. The Office cites *Hong* as teaching that gemifloxacin is a broad spectrum antibiotic that has superior activity against gram-positive strains. *Id.* The Office also states in its discussion of *Hong* that "the present compound also exhibits very potent antibacterial activity against the strains resistant to the known quinolone compounds." *Id. Hohl* and *Kim* are said to teach how gemifloxacin compares to other antibiotics. *Id. Crabb* is cited for teaching the modulation of metabolism of pathogenic bacteria by gemifloxacin. *Id.* The Office states that although the cited references do not teach modulation of the metabolism of *Streptococcus pneumoniae*, "it would have been obvious to one skilled in the art that gemifloxacin would modulate the metabolism of streptococcus pneumoniae [sic] over that of ciprofloxacin in the absence of evidence to the contrary." *Id.* at 5-6. The Office provides no further analysis as to why the combination of references would suggest the claimed invention to one of ordinary skill in the art at the time the invention was made.

The statements by the Office in the rejection of record, however, does not provide a proper basis for rejecting the claims as obvious in view of the combination of prior art references. To establish a *prima facie* case, the Office bears the burden of showing that:

> (1) . . . the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) . . . the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991) (citations omitted). In addition, the combination of references must teach or suggest all of the claim limitations. *In re Royka*, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974).

Here the Office has not provided any explanation as to why the ordinary artisan at the time the invention was made would have been motivated to combine the teachings of the references, or would have had a reasonable expectation that gemifloxacin could be used to modulate the metabolism of ciprofloxacin-resistant *Streptococcus pneumoniae*. It is the Examiner's duty to explain why the combination of the teachings provide the requisite motivation. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). The rejection of record, however, does not provide even a passing reference to why the ordinary artisan would be motivated to specifically select ciprofloxacin-resistant *Streptococcus pneumoniae* for contacting with a gemifloxacin compound. The Office's assertion that the claimed invention would have been obvious "absent evidence to the contrary" also fails to show why, even were the ordinary artisan motivated to contact ciprofloxacin-resistant *Streptococcus pneumoniae* with gemifloxacin, there would be a reasonable expectation that a gemifloxacin compound could modulate the metabolism of not only a specific species of bacteria, but one that is resistant to the related fluoroquinolone ciprofloxacin.

It is only *after* the Examiner has met the initial burden of factually supporting any *prima facie* conclusion of obviousness that Applicant then has any obligation of providing evidence of nonobviousness. *See* M.P.E.P. § 2142. The Office has not met this initial burden. Applicants therefore respectfully submit that the rejection as applied to claims 1, 2, 5-7, 9, 11, and 24-26 is inappropriate and should be withdrawn.

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: December 17, 2004

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